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October 20, 2022

VIA CM/ECF
Honorable Thomas I. Vanaskie, Special Master
Stevens & Lee, P.C.
1500 Market Street, East Tower, 18th Floor
Philadelphia, Pennsylvania 19103

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-02875-RBK (D.N.J.)

Dear Judge Vanaskie:

Plaintiffs object to ZHP's submission regarding Plaintiffs' motion for Rule 37 sanctions, filed months after the close of briefing, which already included an improper sur-reply from ZHP, and long after oral argument was concluded, without leave of Court. There is absolutely no basis for this submission to be considered, and in fact, ZHP offers no justification or basis for the Court to permit the late filing. This submission should be disregarded and to the extent the submission can be deemed a request for leave to file this submission out of time, relief that was not formally or properly requested, that application should be denied.

In addition to the fatal procedural defects, the submission does not move the needle in ZHP's favor even were it to be considered. Boiled down, it is an ipse dixit conclusory opinion that Mr. Chen and ZHP acted in good faith, based on speculative assumptions, as Mr. deLisle does not even state that he spoke with Mr. Chen or anyone else at ZHP, or provide any competent basis for

his assumptions. This includes: (1) in paragraph 25 addressing the failure by Mr. Chen and ZHP to fully disclose the purpose of the request he states, "It is **quite plausible** that a senior company official seeking permission to travel abroad, and worried that the request might be denied, **might well hope** that a seemingly routine request would receive relatively little scrutiny and thus be more likely to win approval." (2) in paragraph 26, "The approach taken to describing the purpose of travel makes still more sense **if** the applicant and his staff saw the initial submission of the Approval form as the first step in a potentially multi-step process where an initial rejection might be revisited." (3) in paragraph 26 speculating as to the purpose of requesting permission to disclose the denied Approval Form, following and only in response to Plaintiffs' request for ZHP to support its refusal to produce Mr. Chen, "**perhaps** as a step toward further efforts to obtain reconsideration or reversal of the denial." (4) in paragraph 29 explaining why the purpose to comply with a District Court Order compelling the deposition was not disclosed, "A request to exit mainland China to be deposed in litigation in a foreign court proceeding raises particular concerns about which a relatively sophisticated applicant **might well worry** (and, in turn, such an applicant would seek to avoid drawing attention to this purpose in a request for permission to travel)." (5) in paragraph 30 speculating as to Mr. Chen's state of mind once again, "A prospective deponent in Chen's position…**could reasonably be concerned that** an application form explicitly stating "deposition" as the purpose for travel might be read by the reviewing authorities as…" (6) in paragraph 31, "Chen and his senior staff at ZHP are l**ikely to be aware of** some or all of the foregoing considerations." and (7) in paragraph 32 speculating as to Mr. Chen's state of mind about and experience in seeking permission to leave China to be deposed without even knowing if this was the first time (Plaintiffs are not aware of another instance), "This **likely includes** the bases for a strong sense of how to apply for an exit permit to provide deposition testimony in litigation

outside China…" (Emphasis added). Nor does he cite to or analyze the laws controlling the application and regulatory entities involved; instead, he just offers assumptions and conclusions.

Of course, missing from the record is any sworn statement from Mr. Chen himself as to what he did, and why, so ZHP's purported expert is speculating as to why Mr. Chen and ZHP acted as they did, in an improper, far out of time, and obviously inadequate effort to create an illusory factual record as a substitute for undisclosed facts within the knowledge of Mr. Chen. All of which was required to be submitted many months ago when the issues were presented to the Court. In fact, he cannot even say that Plaintiffs' arguments are wrong, speculating that Plaintiffs' criticisms do not accurately identify flaws in the effort by Mr. Chen and ZHP to effectuate the Court-ordered deposition at issue: "Plaintiffs' inferences are not **the most plausible** explanations for the rejection of Chen's application…" (deLisle Dec. at 6).

Moreover, ZHP does not seem to have provided Mr. deLisle with Exhibit 27 to Plaintiffs' motion, which shows that Mr. Chen left China in October 2019 to meet with valsartan customers who expected "Mr. Chen [to] express Huahai's regret for what happened and the willingness to listen and make a step towards [redressing the customer's] claims for damage." (ZHP01224767, 1224770). This is clear evidence that the blocking statute hiding Mr. Chen is applied in a biased manner to frustrate the United States Courts, while there is no problem with Mr. Chen leaving the country to promote the commercial interests of ZHP. Mr. deLisle's declaration does not even address this.

The impropriety and inadequacy of this filing is manifest, and the filing should be rejected and not considered, as a similar filing by Mr. Delisle was rejected by another Court. *See Stross v. NetEase*, No. CV 20-00861, 2020 WL 5802419, at *1 (C.D. Cal. Aug. 20, 2020) (**denying "Defendant's Request for Leave to File Supplemental Declaration of Jacques Delisle,**

submitted on August 17, 2020, nearly two weeks after oral argument and more than four months after Defendant filed its Motions to Dismiss to supplement its forum non conveniens argument" (emphasis added)) (Ex. 1 hereto).

The bottom line is that Mr. Chen and ZHP (which the declaration confirms is a "private–that is, non-state-owned" company (deLisle Decl. 5, fn.5)) chose to base the company's operations in China, whereas ZHP's subsidiaries Huahai, US, Inc., Prinston, and Solco are based in New Jersey. Mr. Chen and ZHP understood the political and legal realities of China including the inadequacy of Hague discovery acknowledged in the declaration at footnote 11 stating, "China does not permit attorneys to take depositions in China for use in foreign courts." On the other hand, they were also aware of the requirements of the United States legal system and their obligations to comply with United States law. This Court has already determined that Mr. Chen and ZHP cannot hide behind Chinese law in failing to comply with a District Court Order:

> In looking at the likely effect these PRC laws do and will have on the U.S. market, I find this a most important consideration. Even though between a "legal rock and hard place", PRC defendants cannot enter the U.S. market expecting a possible shield from unfavorable discovery by PRC blocking statutes. As one judge's decision has implied, if you don't like the rules, then stop doing business in the U.S.
>
> Any expectation that a PRC law will successfully shield discovery in a U.S. litigation needs a tempering of realism. That is, PRC defendants must know from the outset they risk serious consequences if and when they fail to obey a U.S. court's order to compel discovery. These consequences arise from the clearly enumerated authority under Rule 37, which U.S. courts wield as needed.
>
> An example of a court imposing such a tempering realism is found *In re Activision Blizzard, Inc.*, []86 A.3d 531, 552 (De. Ch. Ct. 2014). There, the court required French defendants to make a good faith effort to obtain promptly the assistance of the appropriate French authority in deciding the disclosable nature of documents at

> issue. This good faith effort is similar to what I see ZHP has done. However, the Activision court's patience was not infinite in that the French defendants were given a deadline by which the blocked French documents had to be produced, with or without the French authority assistance. The court stated:
>
> > "*If [document] production has not been authorized [by the French authority] by March 31, 2014, when substantial completion of document production is due, then the [French] Defendants shall produce on that date the documents called for by the plaintiff's discovery requests or face the prospect of sanctions in this court. In considering sanctions, the court will be guided by the factors cited in Section 442 of the Restatement [Third of the Foreign Relations Law] and will take into account the recommendation in Section 442(2)(c) of the Restatement that the* ***appropriate sanctions involve making 'findings of fact adverse to a party that has failed to comply with the order for production, even if that party has made a good faith effort to secure permission from the foreign authorities to make the information available and that effort has been unsuccessful.'*** *Restatement § 442(2)(c).*"
>
> Importantly, the non-compliance of a Court Order risks the imposition of Rule 37 sanctions.

In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig., MDL No. 2875, 2021 WL 6010575, at *18-19 (D.N.J. Dec. 20, 2021) (emphasis added) (footnotes omitted) (Ex. 53 to Pls.' Opening Br.) (ECF 1825).

ZHP's brazen submission of Mr. deLisle's declaration demonstrates why a hard line must be drawn. And his own writings do the same. When discussing the "Limits of Consumer

Litigation against Chinese Producers" "particularly where parties seek to take depositions in China," Mr. deLisle wrote, **"The ordinary remedies available to consumers in U.S. law are comparatively ineffective in addressing the large and growing share of harms that come from Chinese (and other) imports."** [1] deLisle & Trujillo, *Consumer Protection in Transnational Contexts*, 58 Am. J. of Comp. L. 135, 161 (2010).

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[1] ZHP's current good manufacturing practices expert David L. Chesney agreed with this concern in his article, titled *Executive Responsibility for Quality*, and during his deposition:

> [Q]uality assurance (QA) and GMP compliance may be viewed differently in the pharmaceutical industry than in those industries where a reputation for high quality drives sales. **QA may be viewed as a "cost of doing business" or an internal "police department" issuing directives that delay or prevent product release. That viewpoint can result in a low priority being assigned to quality operations and resourcing, which can lead in turn to quality problems, regulatory difficulties, unnecessary expense, adverse publicity, lawsuits and investor disappointment.** All these consequences are preventable if executive managers understand the importance of the QA function and treat it as a critical business operation just like other critical areas, such as strategic planning, financial management and others.

Dep. Tr. 236:21-237:22 (emphasis added) (Ex. 2 hereto) (quoting the article (Ex. 3 hereto)). The article concludes:

> **The pharmaceutical industry is globalized as never before in history.** Requirements and expectations of health regulatory authorities may differ somewhat, but **through international bodies such as ICH, regulators are achieving growing consensus about the most critical quality management concepts. First among those is that executive management teams are the key to a company's ability to successfully meet quality standards on a consistent basis**. Doing so is critical to proper clinical performance of the products of this industry and therefore, ultimately, to global public health.
>
> **Prudent management teams recognize this and support their quality units both philosophically and materially, with strong policies backed up by consistent actions, authority and**

Plaintiffs request that this submission be rejected and that the requested sanctions be ordered.

Thank you for your courtesies and consideration.

Respectfully,

ADAM M. SLATER

Encls.

cc: All Counsel (via CM/ECF)

> **resources.** ***Failure to do so may have both serious business consequences for the company and potentially even personal consequences for individual executives.***

(Ex. 3 at 6-7). Mr. Chesney confirmed that Mr. Chen would "fall within the context of top management" facing the consequences. (Dep. Tr. 238:7-11).